

Chapter HSS 165

LABORATORY CERTIFICATION

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Note: Chapters H 37 and H 38 were repealed, Register, September, 1976, and a new chapter H 38 was created effective October 1, 1976. Chapter H 38 was renumbered to be ch. HSS 165, effective May 1, 1982.

**HSS 165.01 Introduction.** (1) **STATUTORY REQUIREMENT.** Section 143.15, Laboratories, approval of, Wis. Stats., requires in part: that laboratories, except physician office laboratories serving not more than 2 physicians, performing clinical laboratory tests or examinations of milk, water, and food products for the purpose of protecting the health of the public shall apply to the department of health and social services for an evaluation of the examinations and appropriate certification; that the certification normally will be valid for 12 months and subject to revocation, denial, or suspension for cause; that the department of health and social services shall establish certification standards; and that laboratories shall not operate without a certificate.

(2) **OTHER PROGRAM RELATIONSHIPS.** In addition to functioning for the attainment of reliable clinical, water, milk, and food product testing, the certification program endeavors to assure the development of clinical and disease control laboratory services to meet the needs and requirements of a number of federal and state health related programs and to achieve better laboratory morbidity reporting systems for disease detection and management. The health related laws or programs receiving input from the laboratory evaluation and certification program include the infant metabolic disorder testing law, alcohol analyses for implied consent and coroner motor vehicle and snowmobile death laws, codes for controlling enteric disease cases and carriers, the Wisconsin Hospital Approval Act, federal Medicare, Medicaid certification, interstate laboratory licensure law, and appropriate municipal, state, and federal laws controlling the quality of laboratory testing services for water, milk, and food products.

(3) **METHOD.** The program shall evaluate and certify laboratories by specialty services offered and provide on-site surveys, technical consultation, other training assistance, and facility certification. The program applies nationally accepted testing procedures and standards to the extent that they exist and are appropriate and special standards as determined or required by other programs such as Medicare, and stresses sat-

isfactory proficiency testing performance in programs approved by the department.

History: Cr. Register, September, 1976, No. 249, eff. 10-1-76; am. Register, October, 1980, No. 298, eff. 11-1-80; am. (2), Register, December, 1981, No. 312, eff. 1-1-82; renum. from H 38.01, Register, April, 1982, No. 316, eff. 5-1-82.

**HSS 165.02 Definitions. In this chapter:**

(1) "Administrative laboratory director" means a person who meets the requirements of s. HSS 165.20 (1) (g) or the requirements of s. HSS 165.20 (3) (b).

(2) "Blood bank" means any facility where activities are conducted involving the drawing, processing, or storage of human blood or blood derivatives, preliminary to transfusion or human use.

(3) "Certification of approval" means a finding by the department that a laboratory is in substantial compliance with the requirements of s. 143.15, Stats., and this chapter.

(4) "Commercial milk laboratory" means a laboratory that offers milk testing services to others for monitoring product quality or for meeting city, county, state, or federal code requirements.

(5) "Department" means the Wisconsin department of health and social services.

(6) "Director" means the person who plans, organizes and directs the operations of the laboratory, including but not limited to training and supervising laboratory personnel, reviewing laboratory procedures and approving test results, and who is responsible for the proper performance of all laboratory procedures.

(7) "Evaluation and certification program" or "certification program" means the laboratory evaluation and certification program of the department.

(8) "Facility" means a clinical laboratory, a blood bank laboratory, or a laboratory engaged in the testing of milk, water, or food products.

(9) "Laboratory" or "clinical laboratory" means a facility where microbiological, biological, physical, serological, chemical, hematological, immunological, cytological, or microscopic examinations of specimens taken from the human body, milk, water, food products, or other matter, are performed for screening, diagnostic, and treatment purposes.

(10) "Laboratory certification advisory council" means the council appointed under s. HSS 165.23.

(11) "Laboratory evaluation" means a system of determining and testing laboratory methods, procedures, and proficiency by inspection of the facility and equipment, review of personnel qualifications, practices, records, and controls, and the use of proficiency testing performance by the department.

(12) "Laboratory specialty" or "specialty" means a science discipline used for the examination of materials derived from the human body or other matter, for the purpose of disease prevention, laboratory screening, diagnosis or treatment of patients, or the examination of milk, water or food products for the purpose of determining purity, potability or

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freedom from harmful substances. For purposes of this chapter, laboratory specialties include but are not limited to the following:

(a) Clinical laboratory specialties, consisting of:

1. Alcohol testing for implied consent;
2. Bacteriology;
3. Clinic microbiology;
4. Mycobacteriology;
5. Mycology;
6. Parasitology;
7. Virology;
8. Routine chemistry;
9. Endocrinology;
10. Toxicology.
11. Urinalysis;
12. Hematology;
13. Cytology;
14. Immunochemistry;
15. General immunology; and
16. Syphilis serology; and

(b) Milk, water, and food laboratory specialties, consisting of:

1. Standard plate count;
2. Inhibitors;
3. Plate loop count;
4. Coliform plate count;
5. Phosphatase testing;
6. Direct microscopic somatic cell count;
7. Optical or electronic somatic cell count;
8. MPN procedure;
9. MF technique;
10. ONPG-MUG (colilert); and
11. Presence-absence.

(13) "Local public health agency laboratory" means a laboratory operated by a single city or county health department, a multiple county health department, or a city-county health department which performs clinical, milk, water, or food tests for the prevention, detection, diagnosis, and control of disease.

(14) "Milk plant laboratory" means a laboratory of a milk plant that functions solely for the purpose of maintaining quality control of the milk plant's products for compliance with city, county, state, and federal statutes, ordinances, rules and regulations.

(15) "Owner" means the person who owns the laboratory facility, the institution operating a laboratory facility, or the state, county, or city agency operating a laboratory facility.

(16) "Participating laboratory" means a laboratory that participates in a proficiency testing program approved by the department.

(17) "Proficiency testing program" means those activities which are required by the department to define, monitor, and measure the accuracy of testing by a laboratory and which meet the applicable requirements of federal agencies for licensure or certification of clinical and milk, water and food laboratories.

(18) "Referee laboratory" means a laboratory that has participated in a proficiency testing program and has shown agreement, reproducibility, and reliability in testing procedures or methods.

(19) "Reference laboratory" means a laboratory of known expertise and reliability.

(20) "Revocation of certification" means the withdrawal of the certification of the laboratory by specialty discipline.

(21) "Suspension of certification" means the temporary withdrawal of the certification of the laboratory by specialty discipline until the cause for suspension is corrected.

History: Cr. Register, September, 1976, No. 249, eff. 10-1-76; cr. (18) (f), Register, January, 1978, No. 265, eff. 2-1-78; am. (1), (2), (7), (8), (14), (16), (17) and (18), renum. (19) to (24) to be (20) to (25), cr. (19), and as renum., am. (21), Register, October, 1980, No. 298, eff. 11-1-80; am. (18) and cr. (18) (b), Register, December, 1981, No. 312, eff. 1-1-82; renum. from H 38.02, Register, April, 1982, No. 316, eff. 5-1-82; r. and recr. Register, October, 1983, No. 334, eff. 11-1-83; am. (12), Register, August, 1992, No. 440, eff. 9-1-92.

**HSS 165.03 Examinations necessary for the protection of the health of the public.** (1) **EXAMINATIONS.** The department designates the following clinical, water, milk, or food examinations as necessary for the protection of the health of the public.

(a) Examinations of body fluids, tissues, discharges, respiratory and environmental air:

1. Microbiology tests
2. Serology tests
3. Chemical tests
4. Hematology tests
5. Immunohematology tests
6. Cytology tests
7. Tests involving radionuclides

(b) Examinations of water:

1. Microbiology tests

(c) Examinations of milk, milk products, and milk containers:

are not available, he is a duly licensed physician designated as administrative laboratory director by the public health agency; or

(c) For laboratories not performing clinical tests, the person holds a bachelor degree with a major in chemistry or microbiology, and has had 2 years' experience in a public health laboratory or other laboratory performing similar milk, water, and food analyses, and has demonstrated knowledge of and performance proficiency using standard methods prescribed for commercial milk, water, food laboratory directors under sub. (2) (a), (c), (d), and (e), or other methods acceptable to the department, and meets existing state and federal requirements for such directors; or

(d) The person was director of an official public health laboratory on July 31, 1975, limits his directorship to those specialties he directed before July 31, 1975, and provided he is approved by the department.

History: Cr. Register, September, 1976, No. 249, eff. 10-1-76; am. (1) (f), Register, January, 1978, No. 265, eff. 2-1-78; am. (1) (a), (e), (f) and (g), r. and recr. (2) (f), Register, October, 1980, No. 298, eff. 11-1-80; cr. (intro.) and r. (2) (g), Register, December, 1981, No. 312, eff. 1-1-82; renum. from H 38.20, Register, April, 1982, No. 316, eff. 6-1-82.

**HSS 165.21 Fees.** (1) **DETERMINATION OF FEES.** Except when increased under sub. (5), each laboratory shall pay an annual fee of \$85 to the department for each specialty in which the laboratory requests certification. This fee does not include costs for proficiency testing, which shall be paid by each laboratory directly to the proficiency testing program provider.

(2) **REFUNDS.** Fees shall not be refundable.

(3) **EXCEPTIONS.** All local public health agency laboratories shall be exempt from fees.

(4) **USE OF FEES.** Fees shall be used to offset the cost to the department for certification of laboratories and the collection of fees.

(5) **FEE REVISION.** Fees under this section may be increased up to a maximum of 8% a year if necessary to support the program. Any fee increase shall be based on a demonstrated need for increased funds to support the level of effort and objects of expenditure in effect on January 1, 1983, and shall be reviewed by the laboratory certification advisory council before taking effect.

History: Cr. Register, September, 1976, No. 249, eff. 10-1-76; r. and recr. Register, January, 1978, No. 265, eff. 2-1-78; r. and recr. (1), r. (2), renum. (3) to (5) to be (4) to (6) and am., Register, October, 1980, No. 298, eff. 11-1-80; am. (1) and (3), Register, December, 1981, No. 312, eff. 1-1-82; renum. from H 38.21, Register, April, 1982, No. 316, eff. 5-1-82; am. (1) (intro.) and (3), cr. (5), Register, October, 1983, No. 334, eff. 11-1-83; r. (1) (a) to (c), renum. (1) (intro.) to be (1) and am., Register, August, 1992, No. 440, eff. 9-1-92.

**HSS 165.22 Injunctions.** The operation or maintenance of a laboratory in violation of s. 143.15, Stats., or rules created thereunder, is prohibited. The department may in addition to other remedies, prosecute an action for an injunction to restrain such violations or to enjoin the future operation of the laboratory until compliance with the section and rules has been obtained. Any lab which operates without a certificate of approval shall be fined not less than \$100 nor more than \$1,000. Each day such violation continues shall constitute a separate offense (s. 143.15 (6), Stats.).

History: Cr. Register, September, 1976, No. 249, eff. 10-1-76; am., Register, October, 1980, No. 298, eff. 11-1-80; renum. from H 38.22, Register, April, 1982, No. 316, eff. 5-1-82.

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HSS 165.23 Advisory council. (1) LABORATORY CERTIFICATION ADVISORY COUNCIL. The department shall establish an advisory council of not more than 9 members, who shall serve for staggered 3 year terms and represent or be the following:

- (a) A physician directed clinical laboratory
- (b) The Wisconsin society of pathologists, inc.
- (c) The Wisconsin hospital association
- (d) The state medical society of Wisconsin
- (e) The Wisconsin association for medical technology
- (f) A public health officer or laboratory director
- (g) A milk, water, or food laboratory director
- (h) The Wisconsin department of natural resources
- (i) A public consumer

(2) RESPONSIBILITIES. The council shall study laboratory certification matters, advise, make recommendations to, and consult with the department.

(3) MEETINGS. The advisory council shall elect a chairperson and meet at least annually or more often at the discretion of the chairperson or petition of any 4 members.

(4) REIMBURSEMENT FOR EXPENSES. Council members shall be reimbursed for their actual and necessary expenses incurred in the performance of their duties.

History: Cr. Register, September, 1976, No. 249, eff. 10-1-76; am. (1) (e), (h) and (i) and (3), Register, October, 1980, No. 298, eff. 11-1-80; renum. from H 38.23, Register, April, 1982, No. 316, eff. 5-1-82.